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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,745	03/18/2004	Tuan Q. Tran	07860004US	5337
7590 McGuire Woods LLP Suite 1800 1750 Tysons Boulevard McLean, VA 22102			EXAMINER PATEL, NIHIR B	
			ART UNIT 3772	PAPER NUMBER
			MAIL DATE 04/15/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/802,745

Applicant(s)

TRAN ET AL.

Examiner

NIHIR PATEL

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01.21.2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 15, 17-22 and 24-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 15, 17-22 and 24-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 21st, 2009 has been entered.

Response to Amendment

2. The examiner acknowledges the amendment filed on January 21st, 2009. Amendment cancels claims 1-11, 13, 14, 16 and 23; amend claim 12; new claims 29-35.

Response to Arguments

3. Applicant's arguments filed on December 10th, 2008 have been fully considered but they are not persuasive. The applicant argues that Walker does not disclose a connection port proximate the bottom of the hollow body configured to connect to an external nebulization chamber, the connection port comprises a nebulizer inlet and a nebulizer outlet; and air flow path, defined by the hollow body and the baffle, having portions antiparallel to one another through the interior of the hollow body. The examiner disagrees with the applicant's argument. The area that connects the breathalyzer chamber 10 to the container 25 is defined as a connection port. The connection port comprises a nebulizer inlet and a nebulizer outlet and air flow path defined by the hollow body and the baffle, having portions antiparallel to one another through an interior of the hollow body.

Claim Objections

4. Claim **34** objected to because of the following informalities: Claim 34 depends from itself. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims **12, 15, 17-22 and 24-35** are rejected under 35 U.S.C. 102(e) as being anticipated by Walker et al. (US 6,679,250).
7. **As to claim 12**, Walker teaches an apparatus that comprises a hollow body having a top and a bottom (see fig. 1; **the area reference character 10 is pointing to is defined as the top; the area where the container 25 is connected to is defined as the bottom**); a connection port proximate the bottom of the hollow body configured to connect to an external nebulization chamber (**the little flange that extends from the bottom part of breathing chamber 10 is defined as the connection port**), the connection port comprising a nebulizer inlet and a nebulizer outlet (**the proximal section of the flange which is defined as the nebulizer outlet; the distal section of the flange is defined as the nebulizer inlet**); a vent **47** proximate the top of the hollow body (see figs. 1, 4a and 4b; col. 5 lines 55-65) configured to receive ambient air when a patient inhales; a baffle **32** at least partially disposed within the hollow body, such that the baffle is configured to be a barrier and wherein the hollow body and the baffle define an air

flow path having portions arranged anti-parallel to one another through an interior of the hollow body (see fig. 1; the arrows in fig. 1 indicate that when the gas hits the baffle 32 it splits into air flow paths (not parallel) and once the gas by-passes the baffle merge into a single air flow path and again split into multiple flow paths once entered the breathing chamber not parallel as the arrows indicate in the breathing chamber); and wherein the drug delivery mouthpiece is structured and arranged such that the patient's inhalation generates an air flow that follows the air flow path defined by the hollow body and the baffle to deliver a medicament to the patient (see fig. 1; col. 5 lines 1-5, 65-67 and col. 6 lines 1-5).

8. As to claim 15, Walker teaches an apparatus wherein the baffle includes a substantially planar member disposed between an intake flow path and a delivery flow path (see figure 1).
9. As to claim 17, Walker teaches an apparatus wherein the baffle is configured to protrude into the external nebulization chamber connected to the connection port (see figure 1).
10. As to claim 18, Walker teaches an apparatus wherein the baffle is configured to direct an airflow to an intake flow path out of the hollow body and into the external nebulization chamber connected to the connection port, and the baffle is configured to direct an airflow toward a delivery flow path from the external nebulization chamber connected to the connection port into the hollow body (see figure 1).
11. As to claim 19, Walker teaches an apparatus that further comprises a delivery conduit arranged proximate the top of the hollow body (see figure 1).
12. As to claim 20, Walker teaches an apparatus wherein the conduit includes an exhaust outlet 11 (see figure 1).

13. **As to claim 21**, Walker teaches an apparatus wherein the exhaust outlet is selectably sealable (see figure 1).
14. **As to claim 22**, Walker teaches an apparatus wherein the exhaust outlet includes a one-way valve (see figure 1).
15. **As to claim 24**, Walker teaches an apparatus that further comprises a delivery conduit arranged between the top of the hollow body and the bottom of the hollow body (see figure 1).
16. **As to claim 25**, Walker teaches an apparatus wherein the vent is sealably configured (see figures 1, 4a and 4b; column 5 lines 55-65).
17. **As to claim 26**, Walker teaches an apparatus wherein the nebulizer is configured to aerosolize a substance (see the summary of the invention).
18. **As to claim 27**, Walker teaches an apparatus wherein the substance includes medicament (see the summary of the invention).
19. **As to claim 28**, Walker teaches an apparatus wherein the vent is configured to exhaust air upon the patient's exhalation. (see figures 1, 4a and 4b; column 5 lines 55-65).
20. **As to claim 29**, Walker teaches an apparatus that comprises a hollow body having a top and a bottom (see fig. 1; the area reference character 10 is pointing to is defined as the top; the area where the container 25 is connected to is defined as the bottom); a connection port proximate the bottom of the hollow body configured to connect to an external nebulization chamber (the little flange that extends from the bottom part of breathing chamber 10 is defined as the connection port), the connection port comprising a nebulizer inlet and a nebulizer outlet (the proximal section of the flange which is defined as the nebulizer outlet; the distal section of the flange is defined as the nebulizer inlet); a vent 47 proximate the top of

the hollow body (see **figs. 1, 4a and 4b; col. 5 lines 55-65**) configured to receive ambient air; a baffle **32** at least partially disposed within the hollow body, wherein the baffle is configured to direct an airflow to an intake flow path out of the hollow body and into the external nebulization chamber connected to the connection port, wherein the baffle is further configured to direct an airflow toward a delivery flow path from the external nebulization chamber connected to the connection port into the hollow body (see **fig. 1**); wherein the drug delivery mouthpiece is structured and arranged such that the patient's inhalation generates an air flow that follows the air flow path defined by the hollow body and the baffle to deliver a medicament to the patient (see **fig. 1; col. 5 lines 1-5, 65-67 and col. 6 lines 1-5**).

21. **As to claim 30**, Walker teaches an apparatus wherein the intake flow path and the delivery flow path are anti-parallel through an interior of the hollow body (see **fig. 1; the arrows in fig. 1 indicate that when the gas hits the baffle 32 it splits into air flow paths (not parallel) and once the gas by-passes the baffle merge into a single air flow path and again split into multiple flow paths once entered the breathing chamber not parallel as the arrows indicate in the breathing chamber**).

22. **As to claim 31**, Walker teaches an apparatus wherein the intake flow path and the delivery flow path are anti-parallel along a substantial portion of an interior of the hollow body (see **fig. 1; the arrows in fig. 1 indicate that when the gas hits the baffle 32 it splits into air flow paths (not parallel) and once the gas by-passes the baffle merge into a single air flow path and again split into multiple flow paths once entered the breathing chamber not parallel as the arrows indicate in the breathing chamber**).

23. **As to claim 32**, Walker teaches an apparatus that further comprises a delivery conduit arranged proximate the top of the hollow body (see figure 1).

24. **As to claim 33**, Walker teaches an apparatus wherein the conduit includes an exhaust outlet 11 (see figure 1).

25. **As to claim 34**, Walker teaches an apparatus wherein the exhaust outlet includes a one-way valve (see figure 1).

26. **As to claim 35**, Walker teaches an apparatus that comprises a hollow body having a top and a bottom (see fig. 1; the area reference character 10 is pointing to is defined as the top; the area where the container 25 is connected to is defined as the bottom); a connection port proximate the bottom of the hollow body configured to connect to an external nebulization chamber (the little flange that extends from the bottom part of breathing chamber 10 is defined as the connection port), the connection port comprising a nebulizer inlet and a nebulizer outlet (the proximal section of the flange which is defined as the nebulizer outlet; the distal section of the flange is defined as the nebulizer inlet); a vent 47 proximate the top of the hollow body (see figs. 1, 4a and 4b; col. 5 lines 55-65) configured to receive ambient air; a baffle 32 at least partially disposed within the hollow body, wherein the baffle is configured to direct an airflow to an intake flow path out of the hollow body and into the external nebulization chamber connected to the connection port, wherein the baffle is further configured to direct an airflow toward a delivery flow path from the external nebulization chamber connected to the connection port into the hollow body (see fig. 1); wherein the the intake flow path and the delivery flow path are anti-parallel through an interior of the hollow body (see fig. 1; the arrows in fig. 1 indicate that when the gas hits the baffle 32 it splits into air flow paths (not

parallel) and once the gas by-passes the baffle merge into a single air flow path and again split into multiple flow paths once entered the breathing chamber not parallel as the arrows indicate in the breathing chamber); a delivery conduit arranged proximate the top of the hollow body (**see figure 1**); and wherein the drug delivery mouthpiece is structured and arranged such that the patient's inhalation generates an air flow that follows the air flow path defined by the hollow body and the baffle to deliver a medicament to the patient (**see fig. 1; col. 5 lines 1-5, 65-67 and col. 6 lines 1-5**).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Nihir Patel/
Examiner, Art Unit 3772

/Michael Brown/
Primary Examiner, Art Unit 3772